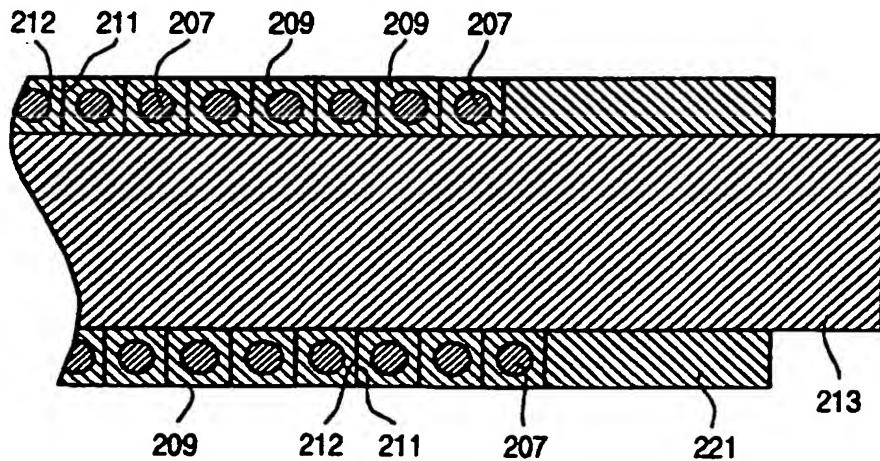


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 25/00		A1	(11) International Publication Number: WO 97/3262 (43) International Publication Date: 12 September 1997 (12.09.97)
(21) International Application Number: PCT/US97/03543		(81) Designated States: AU, CA, JP, European patent (AT, BI, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NI, PT, SE).	
(22) International Filing Date: 7 March 1997 (07.03.97)		Published <i>With international search report.</i>	
(30) Priority Data: 08/612,230 7 March 1996 (07.03.96) US 08/749,683 15 November 1996 (15.11.96) US			
(71) Applicant: HEARTPORT, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US).			
(72) Inventor: SNOW, David, W.; 3555 Partition Road, Woodside, CA 94062 (US).			
(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew L.L.P., 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).			

(54) Title: CANNULA AND METHOD OF MANUFACTURE AND USE



(57) Abstract

An elongate member (207) is coated with a coating (209), preferably by co-extrusion, and the coated elongate member (207) is wound in a helical manner around a mandrel (213). The coated elongate member (207) preferably has a square cross-sectional shape so that adjacent portions of the coated elongate member (207) engage one another when the coated elongate member (207) is wound around the mandrel (213). The coated elongate member (207) is then heated so that the coating (209) on adjacent portions of the coated elongate member (207) fuse together to form an integral structure. Another layer (225) of material may be provided on the radially inner or outer wall of the coated elongate member (207).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TC	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

CANNULA AND METHOD OF MANUFACTURE AND USE

BACKGROUND OF THE INVENTION

The present invention is directed to reinforced hollow tubes and their methods of manufacture and use. A specific application of the present invention is for arterial and venous cardiopulmonary bypass (CPB) cannulas. The present invention is particularly useful as the arterial return cannula for the cardiopulmonary bypass system described in co-pending U.S. Patent Application No. 08/282,192 which is incorporated herein by reference. The CPB system has an arterial return cannula which is used to return oxygenated blood to the patient. An aortic occlusion catheter passes through the arterial cannula. The aortic occlusion catheter is used to block blood flow through the ascending aorta and deliver cardioplegic fluid to arrest the heart for performing surgery on the heart and great vessels. The aortic occlusion catheter is inserted through the same lumen in the arterial cannula which is used to return arterial blood to the patient so that the arterial blood essentially passes in the annular space between the aortic occlusion catheter and the arterial return cannula.

An advantage of the CPB system described above is that only one opening in the patient's arterial system is required for both delivery of cardioplegic fluid and return of arterial blood. In order to achieve optimum blood and cardioplegic fluid flow rates, the wall of the arterial cannula must be minimized while retaining enough structural integrity to prevent kinking and/or cracking. The present invention is particularly useful in providing a thin walled cannula which may be used as an arterial return cannula for the system described above.

A known method of making a reinforced cannula is to dip a mandrel in a polymer solution and wrap a metal wire over the polymer. The mandrel is then dipped again to encase the metal wire between two layers of polymer.

5 Another known method of making a reinforced cannula is to extrude a polymer tubing, wrap a metal wire around the polymer tubing, and extrude another polymer layer over the metal wire.

10 A problem with the known methods of manufacturing a reinforced cannula is that the spacing between adjacent wires must be relatively large to ensure that the polymer flows between adjacent coils so that the two polymer layers bond together to form an integrated structure. Unfortunately, the relatively large spacing requires a relatively thick polymer 15 layer to provide the necessary strength since the wire has a large pitch. The relatively thick polymer layer is also required to ensure that a sufficient amount of polymer is provided to fill the relatively large space. The resulting cannula has a relatively thick wall.

20 Thus, a specific object of the present invention is to provide a new method of manufacturing reinforced tubing and, in particular, cannulas for venous withdrawal and arterial return of blood for a cardiopulmonary bypass system.

25 **SUMMARY OF THE INVENTION**

The present invention solves the problems associated with prior art cannulas by providing a reinforced, thin-walled cannula and a method of manufacturing the reinforced, thin-walled cannula.

30 An elongate member, such as a steel or polymer wire, is coated with a coating, preferably a polymer, thereby forming a coated elongate member. A preferred method of coating the material is to coextrude the material over the elongate member. The coated elongate member is then wound 35 helically around a mandrel and heated so that the coating on adjacent parts of the elongate member bond together. The coated elongate member is then mounted to a cannula body.

In a preferred method, the coated elongate member is formed so that opposing sides of the coated elongate member engage one another when the coated elongate member is wrapped around the mandrel. A preferred cross-sectional shape is 5 substantially square. An advantage of the present invention is that the coating does not need to flow between adjacent portions of the helically-wound member since the coated elongate members are configured to have sides which engage one another. In another aspect of the invention, the coated 10 elongate member is compressed after being wound around the mandrel. The coated elongate member is preferably compressed with a heat shrink tube placed over the coated elongate member before heating. The shrink tube compresses the polymer to further ensure bonding between adjacent portions of the coated 15 elongate member.

In another aspect of the present invention, a layer is positioned over and/or below the coated elongate member. The layer is preferably positioned over the coated elongate member and is applied as a tube of material having a larger 20 inner diameter than the largest outer diameter of the coated elongate member. The tube is expanded, preferably by inflating the tube, and the coated elongate member is positioned inside the tube. The tube is then deflated so that it contracts around the coated elongate member. The tube 25 and coated elongate member are then heated to fuse the elongate member and tube together to form an integrated structure. Although it is preferred to apply the layer as a tube, the layer may also be applied by dipping the coated elongated member in a suitable solution.

30 An advantage of the cannula of the present invention is that the cannula has a thin-walled construction while providing a lumen having a relatively large inner diameter. The lumen is particularly suited to receive an aortic occlusion catheter while still providing enough annular area 35 between the catheter and lumen wall for return of arterial blood to sustain full CPB.

These and other aspects of the invention will become apparent with the following description of the preferred embodiments.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a front view of an arterial cannula and introducer sheath for use with an endoaortic occlusion catheter.

10 Fig. 2 is a cross sectional view of a hemostasis fitting for the arterial cannula and introducer sheath of Fig. 1.

Fig. 3 illustrates the cannula of Fig. 1 with the endoaortic occlusion catheter introduced into the catheter insertion chamber.

15 Fig. 4 illustrates the cannula of Figs. 1 and 2 with the endoaortic occlusion catheter introduced into the patient's femoral artery.

20 Fig. 5 illustrates a multifunction embodiment of the endoaortic occlusion catheter combined with the arterial cannula and introducer sheath.

Fig. 6 is a cross-sectional view of a cannula having a reinforced section coupled to a body.

25 Fig. 7 is a cross-sectional view of a coated elongate member wrapped around a mandrel.

Fig. 8 is a cross-sectional view of the coated elongate member of Fig. 7 after heating and removal from the mandrel.

30 Fig. 9 is a cross-sectional view of a second construction for the reinforced section.

Fig. 10 is a cross-sectional view of a third construction for the reinforced section.

Fig. 11 is a cross-sectional view of a fourth construction for the reinforced section.

35 Fig. 12 is a cross-sectional view of a fifth construction for the reinforced section.

Fig. 13 is a cross-sectional view of a sixth construction for the reinforced section.

Fig. 14 is a cross-sectional view of a seventh construction for the reinforced section.

Fig. 15 is a cross-sectional view of a eighth construction for the reinforced section.

5 Fig. 16 is a cross-sectional view of a ninth construction for the reinforced section.

Fig. 17 shows an exploded view of another arterial return cannula.

10 Fig. 18 shows the distal end of the arterial return cannula of Fig. 17 before heating.

Fig. 19 shows the distal end of the arterial return cannula of Fig. 18 after heating.

15 Fig. 20 shows an enlarged view of the distal end of an obturator used with the arterial return cannula of Fig. 17 along line A-A.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is directed to cannulas and their methods of manufacture. A particularly useful application of 20 the present invention is for arterial and venous cardiopulmonary bypass cannulas.

Referring to Figs. 1-4, an endoaortic occlusion catheter 95 is coupled to a cannula 50 that is configured to serve as an arterial bypass cannula and an introducer sheath 25 for introduction of the endoaortic occlusion catheter 95. By configuring the catheter 95 and cannula 50 in this manner, both devices are inserted through the same arterial opening which minimizes trauma to the patient. Use of the cannula 50 to receive an aortic occlusion catheter is merely an example 30 of a use of the present invention and the cannula 50 may be used for any other purpose. Furthermore, the term cannula as used herein refers to any hollow body structure, such as a catheter or trocar, which is inserted into a patient's vascular system. The cannula 50 is coupled to a 35 cardiopulmonary bypass system (not shown) for delivering oxygenated blood to the patient's arterial system. The aortic occlusion catheter 95 has a lumen which is coupled to a source of cardioplegic fluid (not shown). The lumen is coupled to an

outlet which is distal to the balloon 96. Cardioplegic fluid is delivered through the lumen and outlet for arresting a patient's heart when the patient is on full cardiopulmonary bypass. The balloon 96 occludes the ascending aorta to prevent oxygenated blood from reaching the coronary arteries and starting the heart prematurely.

The cannula 50 has a body 51 which is preferably made of a transparent, flexible, biocompatible polyurethane elastomer or similar material. In one preferred embodiment, the body 51 has a 45° beveled distal end 53, a proximal end 52, a blood flow lumen 57 extending between the proximal end 52 and the distal end 53, and an outflow port 91 at the distal end 53. Alternatively, the body 51 can have a straight cut distal end with a chambered or rounded edge. Optionally, a plurality of additional outflow ports may be provided along the length of body 51, particularly near distal end 53. The body 51 is tapered from the proximal end 52 to the distal end 53 and, in one preferred embodiment, the tapered body 51 is reinforced with a coil of flat stainless steel wire 54 embedded in the wall of the body 51. Adjacent to the proximal end 52 of the body 51, proximal to the reinforcing coil 51, is a clamp site 51 which is a flexible section of the body 51 that can be clamped with an external clamp, such as a Vorse type tube occluding clamp, forming a hemostatic seal to temporarily stop blood flow through the lumen 57 of the cannula 50. In a preferred embodiment, the body 51 has a length between about 10 cm and 60 cm, and preferably between about 12 cm and 30 cm. In one particular embodiment, the body 51 has a distal external diameter of approximately 7 mm or 21 French (Charrière scale) and a distal internal diameter of approximately 6.0 mm or 18 French. In a second particular embodiment, the body 51 has a distal external diameter of approximately 7.7 mm or 23 French (Charrière scale) and a distal internal diameter of approximately 6.7 mm or 20 French. Preferably, the proximal end 52 of the body 51 of either embodiment has an internal diameter of approximately 3/8 inch or 9.5 mm. The choice of which embodiment of the cannula 50 to use for a given patient will depend on the size of the

patient and the diameter of the artery chosen for the arterial cannulation. Generally, patients with a larger body mass will require a higher infusion rate of oxygenated blood while on cardiopulmonary bypass, therefore the larger arterial bypass cannula 50 should be chosen if the size of the artery allows.

An adapter assembly 65 is connected to the proximal end 52 of the body 51. In one preferred embodiment, the adapter assembly 65 and the body 51 are supplied preassembled as a single, sterile, ready-to-use unit. Alternatively, the adapter assembly 65 can be packaged and sold as a separate unit to be connected to the body 51 at the point of use. The adapter assembly 65 has a Y-fitting 58 which is connected to the proximal end 52 of the cannula body 51. The Y-fitting 58 has a first branch ending in a barbed connector 59 which is configured for fluid connection to tubing 92 from a cardiopulmonary bypass system, as shown in Fig 4. To prepare the arterial bypass cannula 50 for insertion into a peripheral artery, such as a patient's femoral artery or brachial artery, by an arterial cutdown or by a percutaneous Seldinger technique, a connector plug 71, which is molded of a soft, elastomeric material, is placed over the barbed connector 59. A tapered dilator 67 is passed through a wiper-type hemostasis seal 72 in the connector plug 71. The wiper-type hemostasis seal 72 is a hole through the elastomeric connector plug 71 that has a slight interference fit with the external diameter of the dilator 67. A series of ridges can be molded within the hemostasis seal 72 to reduce the sliding friction on the dilator 67 while maintaining a hemostatic seal. It is understood that any other type of hemostasis seal 72 may be used with the present invention. The dilator 67 has a tapered distal tip 69, a proximal hub 70 with a luer lock connector, and a guidewire lumen 79, sized for an 0.038 inch diameter guidewire, that runs from the distal tip 69 to the proximal hub 70. The diameter of the dilator 67 is such that the dilator 67 substantially fills the cannula lumen 57 at the distal end 53 of the cannula body 51. The length of the dilator 67 is such that the distal tip 69 of the dilator 67 extends approximately 2 to 5 cm, and more preferably 4 to 5

cm, beyond the beveled end 53 of the body 51 when the dilator hub 70 is against the connector plug 70. The dilator 67 may assume a bend 73 in it at the point where the dilator 67 passes through the Y-fitting 58 when the dilator 67 is fully 5 inserted. One or more depth markers 74, 75 can be printed on the dilator 67 with a nontoxic, biocompatible ink. One depth marker 74 may be placed so that, when the marker 74 is just proximal to the hemostasis seal 72 on the elastomeric connector plug 71, the tapered distal tip 69 of the dilator 67 10 is just emerging from the beveled end 53 of the body 51. In one particular embodiment, the tapered dilator 67 is made of extruded polyurethane with a radiopaque filler so that the position of the dilator can be verified fluoroscopically.

A second branch of the Y-fitting 58 is connected to an 15 extension tube 62 which terminates in a hemostasis valve 76 configured to receive the endoaortic occlusion catheter 95 therethrough (Figs. 3 and 4). The extension tube 62 has a flexible middle section which serves as a proximal clamp site 64 that can be clamped with an external clamp, such as a Vorse 20 type tube occluding clamp, forming a hemostatic seal to temporarily stop blood flow through the lumen 63 of the extension tube 62. The lumen 63 of the extension tube 62 between the proximal clamp site 64 and the hemostasis valve 76 serves as a catheter insertion chamber 66, the function of 25 which will be more fully explained in connection with Fig. 3. The hemostatic seal may, of course, be any other type of seal.

In a preferred embodiment of the arterial bypass cannula 50, the hemostasis valve 76 is a type of compression fitting known in the industry as a Tuohy-Borst adapter, 30 however, any other suitable seal may be used. The adapter 76 is shown in greater detail in Fig. 2. The adapter 76 has a compressible tubular or ring-shaped elastomeric seal 83 that fits within a counterbore 79 in the fitting body 77. The elastomeric seal 83 is preferably made from a soft, resilient, 35 self-lubricating elastomeric material, such as silicone rubber having a hardness of approximately 20-50 and preferably 40-50 Shore A durometer. The elastomeric seal 83 has a central passage 84 with a beveled entry 85 on the proximal end of the

passage 84. The elastomeric seal 83 has a beveled distal surface 86 angled at about 45° which fits against a tapered seat 80 in the bottom of the counterbore 79 that is angled at about 60°. A threaded compression cap 87 screws onto the fitting body 77. The threaded cap 87 has a tubular extension 89 which fits within the counterbore 79 in the fitting body 77. An externally threaded section 88 on the proximal end of the tubular extension 87 engages an internally threaded section 81 within the proximal end of the counterbore 79.

5 When the threaded cap 87 is screwed down onto the fitting body 77, the tubular extension 89 bears on the elastomeric seal 83 forcing it against the tapered seat 80 of the counterbore 79. The resultant force on the elastomeric seal 83 squeezes the elastomeric seal 83 inward to close off the passage 84 to make

10 a hemostatic seal. When the threaded cap 87 is unscrewed again from the fitting body 77, the central passage 84 of the elastomeric seal 83 opens up again. The deliberate 15° mismatch between the angle of the beveled distal surface 86 of the elastomeric seal 83 and the tapered seat 80 of the

15 counterbore 79 prevents the elastomeric seal 83 from binding and causes the passage 84 to open up reliably when the threaded cap 87 is unscrewed from the fitting body 87. An internal ridge 90 within the threaded cap 87 engages in a snap fit with an external ridge 82 on the proximal end of the

20 fitting body 77 to keep the threaded cap 87 from being inadvertently separated from the fitting body 77 if the threaded cap 87 is unscrewed to the point where the threads 88, 81 are no longer engaged.

25

In one particular embodiment, the central passage 84 of the elastomeric seal 83 has an internal diameter of about 5 mm to allow clearance for inserting a catheter 95 with a shaft diameter of 3-4 mm through the adapter 76 without damaging the occlusion balloon 96 mounted on it. The adapter 76 is adjustable through a range of positions, including a fully open position for inserting the balloon catheter 96, a partially closed position for creating a sliding hemostatic seal against the shaft 97 of the catheter 95, and a completely closed position for creating a hemostatic seal with no

catheter in the passage 84. In an alternative embodiment, the passage 84 of the elastomeric seal 83 can be sized to have a slight interference fit with the shaft 97 of the catheter 95 when uncompressed. In this embodiment, the adapter 76 has 5 positions which include a fully open position for creating a sliding hemostatic seal against the shaft 97 of the catheter 95, and a completely closed position for creating a hemostatic seal with no catheter in the passage 84. In a second 10 alternative embodiment, a separate ring-like wiper seal (not shown) is added in series with the adapter 76 to create a passive sliding hemostatic seal against the shaft 97 of the catheter 95 without the necessity of tightening the threaded cap 87. Additionally, the adapter 76, in either embodiment, 15 may have a tightly closed position for securing the catheter shaft 97 with respect to the patient. In other alternative embodiments, other known hemostasis valves may be substituted for the Tuohy-Borst adapter 76 as just described.

In a particularly preferred embodiment, the internal surface of the lumen 63 of the extension tube 62 and/or the 20 internal surface of the lumen 57 of the body 51 are coated with a highly lubricious biocompatible coating, such as polyvinyl pyrrolidone, to ease the passage of the endoaortic occlusion catheter 95, and especially the occlusion balloon 96, through these lumens. Other commercially available 25 lubricious biocompatible coatings can also be used, such as Photo-Link™ coating available from BSI Surface Modification Services of Eden Prairie, MN; sodium hyaluronate coating available from Biocoat of Fort Washington, PA; proprietary silicone coatings available from TUA of Sarasota, FL; and 30 fluid silicone or silicon dispersions. Similarly, a distal portion of the exterior of the body 51 can be coated with one of these lubricious biocompatible coatings to facilitate insertion of the arterial bypass cannula 50 into the artery at the cannulation site. Furthermore, the endoaortic occlusion 35 catheter 95 itself, in any of the embodiments described herein, can be coated with one of these lubricious biocompatible coatings to facilitate its insertion and passage through the arterial bypass cannula 50 and the patient's

5 vasculature. Preferably, the occlusion balloon 96 of the endoaortic occlusion catheter 95 should be free of any lubricious coating so that there is sufficient friction between the expanded occlusion balloon and the interior aortic wall to prevent accidental dislodgement or migration of the occlusion balloon 96.

In operation, the arterial bypass cannula 50 is prepared for insertion as shown in Fig. 1, with the tapered dilator 67 in place in the blood flow lumen 57 of the body 51 and with the fitting 76 completely closed. An arterial cutdown is made into an artery, preferably the patient's 10 femoral artery, at the cannulation site or a guidewire is placed percutaneously using the Seldinger technique and the dilator 67 and the distal end 53 of the body 51 are inserted 15 into the lumen of the artery with the bevel up. A suture 94 can be tied around the artery 93 where the body 51, as shown in Fig. 3, inserts to avoid bleeding from the artery 93 at the cannulation site. The dilator 67 is then withdrawn from the body 51, allowing blood to flash back and fill the lumen 57 of 20 the body 51. When the tip 68 of the dilator 67 is proximal to the distal clamp site 56 an external clamp is applied to the distal clamp site 56 to stop further blood flow. The dilator 67 is completely withdrawn and the connector plug 71 is 25 removed so that a tube 92 from the cardiopulmonary bypass system can be attached to the barbed connector 59 of the Y-fitting 58, as shown in Fig. 33. Air is bled from the arterial bypass cannula 50 by elevating the extension tube 62 and opening the fitting 76 slightly and releasing the external 30 on the distal clamp site 56 to allow the blood to flow out through the fitting 76. Alternatively, air can be bled out of the arterial bypass cannula 50, through an optional vent fitting with a luer cap (not shown) that can be provided on the Y-fitting 58 or an infusion line and a three-way stopcock. The optional vent fitting can be also used as a port for 35 monitoring perfusion pressure within the arterial bypass cannula 50. Once the air is bled out of the system, the external clamp can be removed from the distal clamp site 56 the cardiopulmonary bypass system pump can be turned on to

perfuse the patient's arterial system with oxygenated blood at a rate of about 3 to 6 liters/minute, preferably at a pump pressure of less than about 500 mm Hg.

To introduce the endoaortic occlusion catheter 95 into the arterial bypass cannula 50, an external clamp 91 is placed on the proximal clamp site 64, as shown in Fig. 3, to stop blood from flowing out through the extension tube 62 and the adapter 76 is opened all the way by unscrewing the threaded cap 87 to open up the passage 84 through the elastomeric seal 83. The distal end of the endoaortic occlusion catheter 95 with the occlusion balloon 96 mounted thereon is inserted through the passage 84 of the adapter 76 into the insertion chamber 66 of the arterial bypass cannula 50. Optionally, first and second depth markers 98, 99 may be printed on the shaft 97 of the endoaortic occlusion catheter 95 with a nontoxic, biocompatible ink. The first depth marker 98 on the catheter 95 indicates when the occlusion balloon 96 is entirely distal to the elastomeric seal 83. When the first depth marker 98 is positioned just proximal to the threaded cap 87, the adapter 76 should be tightened to create a sliding, hemostatic seal around the catheter shaft 97. Now, the clamp 91 can be removed to allow the catheter 95 to be advanced distally through the arterial bypass cannula 50.

Before the endoaortic occlusion catheter 95 enters the blood flow lumen 57 within the Y-fitting 58, the perfusion rate from the cardiopulmonary bypass system pump should be temporarily turned down to a rate of about 1 to 2 liters/minute to avoid hemolysis, tubing disruptions or other complications due to the additional flow resistance caused by the occlusion balloon 96 as it passes through the blood flow lumen 57. The catheter 95 can now be advanced distally until the occlusion balloon 96 is distal to the distal end 53 of the body 51. A second depth marker 99 on the catheter 95 indicates when the occlusion balloon 96 is entirely distal to the distal end 53 of the body 51. When the second depth marker 98 reaches the proximal end of the threaded cap 87, as shown in Fig. 3, the perfusion rate from the cardiopulmonary bypass system pump should be returned to a rate of about 3 to

6 liters/minute. The endoaortic occlusion catheter 95 can now be advanced into the ascending aorta for partitioning the heart and inducing cardioplegic arrest according to the methods described above. When the endoaortic occlusion 5 catheter 95 is in position within the ascending aorta the adapter 76 can be tightened around the catheter 95 to act as a friction lock to hold the catheter in place.

After completion of the surgical procedure on the heart, the endoaortic occlusion catheter 95 can be removed 10 from the cannula 50 by reversing the sequence of operations described above. The cannula 50 can remain in place until the patient has been weaned from cardiopulmonary bypass, then the cannula 50 can be removed and the arterial puncture site repaired.

15 It should be noted that for the venous side of the cardiopulmonary bypass system, a similar dual purpose venous bypass cannula and introducer sheath with the above-described features can be used for accessing the femoral vein and for introducing a venting catheter or other devices into the 20 venous side of the circulatory system. In a venous configuration the dual purpose venous bypass cannula and introducer sheath preferably has an external diameter of about 21 to 32 French units, an internal diameter of about 18 to 30 French units, and a length of about 50 to 75 cm.

25 It should be noted that while several aspects of the present invention have been illustrated and discussed separately in the foregoing description, many of these aspects can be advantageously combined into a single, multifunction embodiment. As an illustrative example, Fig. 5 shows a 30 multifunction embodiment of the endoaortic occlusion catheter 160 combining several of the inventive aspects previously discussed. As discussed above, however, any other aortic occlusion catheter may be used and preferred aortic occlusion catheters are described in U.S. Patent Application 08/692,992. 35 The shaft 164 of the catheter 160 has a coaxial construction with an inner 161 and outer 162 tubular member. The shaft 164 may be made with varying degrees of stiffness along the length of the shaft 164, culminating in a softatraumatic tip 165

which may be highly loaded with a radiopaque filler. The shaft 164 may be made with a precurved distal portion 166 or with a precurved distal portion 166 which is out of plane with the proximal portion of the shaft 164. An expandable 5 occlusion balloon 163 is mounted on the distal portion 166 of the shaft 164. The balloon 163 preferably has a low profile deflated state with an ellipsoidal shape. In addition, the balloon 163 may have an eccentric or asymmetrical inflated profile 163' which would also provide a steering means for the 10 distal tip of the catheter.

The occlusion balloon 163 is mounted with its distal balloon neck 167 attached to the inner tubular member 161 and its proximal balloon neck attached to the outer tubular member 162. The inner tubular member 161 is attached at its proximal 15 end to a first hub 171 and the outer tubular member 162 is attached at its proximal end to a second 169 hub 171 which are axially slidably and/or rotatable with respect to one another. An infusion fitting 177, such as a luer lock, on the first hub 171 is connected to an infusion lumen 178 which terminates at 20 the distal end of the catheter 160. An inflation fitting 170, preferably a luer lock, on the second hub 171 is connected to an inflation lumen 179 defined by an annular space between the inner 161 and outer 162 tubular members which communicates with the interior of the occlusion balloon 163.

25 The second hub 169 may be moved proximal and/or rotated with respect to the first hub 171 to minimize the deflated profile of the occlusion balloon 163. The lower deflated profile of the occlusion balloon 163 facilitates easy insertion of the catheter 160 through a dual function arterial 30 cannula and introducer sheath 50. When the endoaortic occlusion catheter 160 is combined with the dual function arterial cannula and introducer sheath 50, the shaft 164 of the catheter 160 should be made with an additional 20-25 cm of length for a total shaft length of approximately 100-115 cm. 35 The diameter of the catheter shaft 164 should also be minimized as much as possible to reduce the amount of cross sectional area the catheter shaft 164 takes up in the blood flow lumen of the arterial cannula 50. To this end, this

combined embodiment is made with a distal pressure transducer 172 and a balloon pressure monitoring transducer 173 mounted on the inner tubular member 161. The distal pressure transducer 172 and the balloon pressure monitoring transducer 173 are electrically connected to an electrical connector 174 on the first hub 171. Also on the first hub 171 is a fiberoptic connector 176 which connects to a fiberoptic bundle 175 which terminates with a means for directing a lateral beam of light at the distal end of the catheter 160 for aortic transillumination and/or for facilitating nonfluoroscopic placement of the catheter 160. The fiberoptic bundle 175 may also be made as a separate unit for insertion through the infusion lumen 178 of the catheter 160 to further reduce the catheter shaft diameter while maintaining maximum functionality. The diameter of the catheter shaft 164 can thus be reduced to as small as 8 to 10.5 French (2.7-3.5 mm diameter).

Referring to Fig. 6, a cross-sectional view of another preferred cannula 201 is shown. A specific application of the present invention is for arterial and venous cannulas for a cardiopulmonary bypass system. The methods and devices described herein in connection with arresting a patient's heart and placing the patient on cardiopulmonary bypass are incorporated here for use with the cannula 201 described below and any other cannula described herein. The cannula 201 includes a body 203 and a reinforced section 205. As will be discussed in greater detail below, the reinforced section 205 has a thin wall which maximizes the lumen size for a given outer diameter.

Referring to Fig. 7, an apparatus for forming the reinforced section 205 is shown. The reinforced section 205 of the cannula 201 is preferably manufactured with an elongate member 207 coated with a coating 209. The elongate member 207 may be made of any suitable material which has the requisite structural characteristics such as stainless steel, nickel titanium, or a polymer. A preferred material is 304V stainless steel wire having a 0.008 inch diameter. The

elongate member 207 may have any cross-sectional shape and a preferred shape is circular.

The elongate member 207 is preferably coated with the coating 209 by coextruding the elongate member and the coating 209. Any suitable coating 209 may be used and preferred coatings include polymers and specifically polyurethane, PVC, polyether block amide which can be purchased from Elf Atochem Inc. under the name **PEBAX**, and styrene block copolymer which can be purchased from Shell under the name **KRATON**. A preferred polyurethane is polytetramethylene glycol ether which can be purchased from Dow under the name **Dow 2363 PELLETHANE 80AE**.

The coating 209 is extruded over the elongate member 207 so that the coating 209 has opposing sides 211, 212 which are configured to engage one another when the coated elongate member 207 is wrapped around a mandrel 213. A preferred shape is a quadrangle, and specifically a square, however, any other shape may be used including irregular shapes so long as the opposing sides 211, 212 are configured to engage one another. The square cross-sectional shape preferably has sides having lengths between 0.010 and 0.020 inch and more preferably between 0.010 and 0.015 inch and most preferably 0.014 inch. The relative dimensions for the thickness of the cannula has been exaggerated as compared to the inner diameter for clarity with the actual dimensions being provided herein.

The coated elongate member 207 is wrapped around the mandrel 213 in a helical shape. The mandrel 213 is preferably coated with a lubricious coating such as TFE to prevent sticking. An advantage of the present invention over other methods of forming a cannula is that the coating 209 encasing the reinforcing member 207 does not have to flow between adjacent portions of the elongate member 207 since the elongate member 207 is coextruded to have a shape in which the opposing sides 211, 212 already engage one another. A shrink tube (not shown), preferably a heat shrink tube such as a polyester or fluorinated ethylene propylene (FEP) tube, may also be positioned around the elongate member 207 to facilitate bonding. The shrink tube is preferably removed

after heating. The wound coated elongate member 207 may also be dipped in a polymer solution such as polyurethane and tetrahydrofuran (solvent) to enhance the structural characteristics of the reinforced section 205. Furthermore, 5 the coating or tube may also be applied over the wound coated elongate member. Alternatively, a tube may be positioned over the mandrel 213 and the coated elongate member 207 may be wound over the tube. The reinforced section 205 may be made of more than one layer of the coated elongate member 207 and 10 the coated elongate member 207 may be wrapped in different directions to increase the hoop and tensile strength. Although it is preferred that the elongate member 207 has a constant cross-sectional profile, the elongate member 207 may also have differing sizes to provide stiff and flexible areas. 15

After the coated elongate member 207 has been wrapped around the mandrel 213, the coated elongate member 207 is heated to melt the coating 209 and fuse adjacent portions of the coating 209 together to form an integrated structure. The coated elongate member 207 is preferably heated using an 20 oven, however, any other heating method may be used including an IR lamp, heating the mandrel 213, or a combination thereof. The coated elongate member 207 is then cooled and removed from the mandrel 213 thereby forming the reinforced section 205 of the cannula 201.

25 Referring to Fig. 8, the resulting reinforced section 205 is shown. The coating 209 on the elongate member 207 fuses together so that the coating 209 forms a matrix which is reinforced by the elongate member 207. Although it is preferred to heat the coated elongate member 207 to fuse 30 the material together, the coated elongate member may also be coated with a solvent before winding the coated elongate member around the mandrel. The solvent would fuse the adjacent material together and would flash off leaving the fused material.

35 Referring again to the cross-section of Fig. 6, the reinforced section 205 has a lumen 215 therethrough for delivering or withdrawing fluids from a patient. The reinforced section 205 is attached to the body 203 by any

method and is preferably bonded to the body 203 by insert molding. The body 203 includes a lumen 217 which is fluidly coupled to the lumen 215 of the reinforced section 205. The body 203 has been simplified and may include valves, a Y-connection, luer connections or any other features.

5 Furthermore, the body 203 is preferably configured to engage a 3/8 inch fitting which is a standard size for cardiopulmonary bypass systems. The lumen 215 of the reinforced section 205 may be any size but preferably has an internal diameter of at 10 least 0.180 and more preferably at least 0.236 and most preferably at least 0.242 but no more than 0.375 inch.

15 A distal end 219 of the cannula 201 has an atraumatic tip 221 for introduction into the patient. The atraumatic tip 221 is preferably an integral extension of the coating 209 (see Fig. 8) extending beyond the reinforced section 205. The atraumatic tip 221 has a length of at least 0.050 and a thickness adjacent to the reinforced section which is preferably the same as the reinforced section.

20 A proximal end 223 of the reinforced section 205 is flared outward slightly so that the proximal end 223 has a larger lumen than the distal end 219. The proximal end 223 preferably forms an angle of between 2° and 10° and more preferably between 4° and 6° with respect to a longitudinal axis of the cannula 201.

25 The cannula 201 is particularly useful for arterial return and venous drainage cannulas for the cardiopulmonary bypass system described above since the cannula 201 can be manufactured with a thin wall. As such, the reinforced section 205 preferably has a thickness between 0.010 and 0.025 inch and more preferably between 0.013 and 0.020 inch and most preferably between 0.014 and 0.017 inch. The preferred thickness provides the necessary structural characteristics while maximizing the lumen size so that flow rates through the cannula are optimized. The cannula 201 of the present 30 invention also has a unique spacing between adjacent portions of the coated elongate member. Referring to Fig. 8, a gap K between adjacent portions of the elongate member 207 is preferably less than 0.019 inch and more preferably less than 35

0.006 inch and most preferably less than 0.004 inch. A centerline spacing L between adjacent portions of the elongate member 207 is preferably less than 0.022 inch and more preferably less than 0.018 inch and most preferably less than 5 0.014 inch.

Referring to Fig. 9, a second preferred construction is shown for the reinforced section 205. The elongate member 207 and coating 209 are preferably the same as described above in connection with Figs. 7-8, however, another layer 225 is 10 positioned either over the elongate member 207 or below the elongate member 207 to increase the strength of the reinforced section 205. When the layer 225 is on the radially inner wall of the cannula 201, the layer 225 may be applied by dipping the mandrel 213 in a suitable solution, extruding the layer 15 over the mandrel 213 or positioning a tube over the mandrel 213. The coated elongate member 207 is then wrapped around the mandrel 213 and heated to fuse the coating 209 and layer 225 together. When the layer 225 is on the radially outer wall of the cannula, the layer 225 may be applied by dipping 20 the coated elongate member 207 in a suitable solution after wrapping the coated elongate member 207 around the mandrel 213, extruding the layer 225 over the coated elongate member 207 wound around the mandrel 213, or positioning a tube over the coated elongate member wound around the mandrel 213 and 25 fusing it to the coated elongate member. The coated elongate member 207 and coating 209 have the same preferred dimensions described above. The layer 225 has thickness of no more than 0.007 inch and more preferably between 0.001 and 0.003 inch and is preferably made of the same materials as the coating 30 209 described above. Fig. 9 depicts the reinforced section 205 before heating, however, after heating the polymer layer 225 and coating 209 fuse together to form an integrated structure.

Referring to Fig. 10, a third preferred construction 35 for the reinforced section 205 is shown. The reinforced section 205 is made according to the same procedure described above except that a different elongate member 207A is used. The elongate member 207A is preferably made of metal and has a

quadrangle shaped cross-section. A preferred elongate member is a stainless steel flat wire having cross-sectional dimensions of 0.005 inch by 0.020 inch. The elongate member 207A is preferably coextruded with the coating 209 to a thickness of 0.003 all around although any thickness may be used. A layer 225A, which is preferably the same as the layer 225 described above, may be positioned on the radially inner or outer wall of the cannula. The resulting structure yields an inner diameter of at least 0.180 inch, more preferably at least 0.236 inch, and most preferably at least 0.242 inch and no more than 0.375 inch. The resulting reinforced section 205 has a thickness of 0.011 inch without the layer 225A and 0.013 inch with the layer 225A. The reinforced section 205 may also be formed without the layer 225A so that the wall thickness of the cannula is minimized. Fig. 10 depicts the reinforced section 205 before heating, however, after heating the layer 225A and coating 209 fuse together to form an integrated structure.

Referring to Fig. 11, a fourth preferred construction for the reinforced section 205 is shown. The reinforced section 205 is made according to the same procedure described above and has the same elongate member 207 as described in connection with Fig. 70. The coating 209B has an overlapping portion 227 which lies over an adjacent portion of the coated elongate member 207B. The elongate member 207B is a 0.005 inch by 0.020 inch stainless steel flat wire, and the coating has a width of 0.003 inch all around the elongate member 207. The overlapping portion 227 has a thickness of 0.005 inch and a length of 0.013 inch. The overlapping portion 227 provides an interlocking relationship between adjacent portions of the coated elongate member 207. Fig. 11 depicts the reinforced section 205 before heating, however, after heating the material from adjacent portions of the coating 209 and the overlapping portion 227 fuse together to form an integrated structure.

Referring to Fig. 12, a fifth preferred construction for the reinforced section 205 is shown. The fifth preferred construction differs from the first through fourth preferred

constructions in that the elongate member 207C is not coated before being wrapped around the mandrel. As discussed above, a known method of manufacturing reinforced tubing is to extrude a tube, mount the tube on a mandrel, wind a metal coil around the tube and position another tube over the coil. The tubes and coil are then heated so that the inner and outer tubes bond together. A problem with the known method is that relatively thick walled tubes are formed since the layers must be relatively thick to ensure sufficient strength since the wire must be spaced apart.

The elongate member 207C of Fig. 12 is made of a polymer, preferably 75D polyurethane, so that radially inner and outer polymer layers 229, 231 can fuse to the elongate member 207C to form an integrated structure. Thus, the polymer layers 229, 231 do not need to fuse together completely to form an integrated structure which overcomes a problem with prior art methods of forming reinforced cannulas. The polymer layers 229, 231, preferably 80A polyurethane, are positioned on opposite sides of the polymer elongate member 207C. The polymer layers 229, 231 are preferably softer than the polymer used for making the elongate member 207C. The elongate member 207C preferably has a diameter between 0.005-0.020 inch and more preferably between 0.008 and 0.012 inch. The layers 229, 231 preferably have a thickness of 0.002 to 0.015 inch and more preferably 0.005 to 0.10 inch. The elongate member 207C is preferably wound so that adjacent portions of the elongate member 207C contact one another, however, the polymer elongate member 207C may be wound so that a space exists between adjacent portions of the elongate member 207C. Furthermore, although the elongate member 207C preferably has a circular cross-sectional shape the elongate member 207C may have any other shape. The polymer layers 229, 231 may be applied in any manner including coextrusion, dipping or by simply using pre-formed tubes.

The polymer layers 229, 231 are preferably heated so that they bond with the elongate member 207C. The polymer layers 229, 231 are preferably positioned on both sides of the elongate member 207C before heating the layers 229, 231,

however, the layers 229, 231 may also be applied one at a time. By constructing the reinforced section 205 in this manner, the polymer does not need to flow completely between each part of the elongate member 207C to provide an integrated structure since the layers 229, 231 must simply bond to the elongate member 207C rather than having to bond with the opposing layer 229, 231. Fig. 12 depicts the reinforced section 205 before heating, however, after heating the polymer material from the layer 225A and coating 209 fuse together to form an integrated structure.

Referring to Fig. 13, a sixth preferred construction for the reinforced section 205 is shown with polymer and metal elongate members 207D, 207E wound together. Two polymer layers 229D, 231D are positioned on opposite sides of the elongate members 207D, 207E and may be provided in any manner described above. The polymer layers 229D, 231D are preferably softer than the polymer elongate member 207D. A preferred material for the polymer layers 229D, 231D is 75D polyurethane and a preferred material for the polymer elongate member 207D is 80A polyurethane. The soft polymer layers 229D, 231D are melted to bond to the polymer elongate member 207D thereby forming an integrated structure. The metal elongate member 207E provides structural strength and is preferably a stainless steel wire although any metal may be used. Although it is preferred that the elongate members 207D, 207E have circular cross-sectional shapes, the elongate members may have any other shape. Furthermore, although it is preferred that the elongate members have the same cross-sectional shape, the elongate members may also have different cross-sectional shapes. Fig. 13 depicts the reinforced section 205 before heating, however, after heating the material from the layers 229D, 231D and the elongate member 207D will fuse together to form an integrated structure.

Referring to Fig. 14, a seventh preferred construction for the reinforced section 205 is shown. A polymer elongate member 207F is wound together with a flat elongate member 207G. The polymer material for the polymer elongate member 207F may be any polymer and is preferably 75D

polyurethane. The flat elongate member 207G is preferably the same as the elongate member 207A described above in connection with Fig. 10. Two layers of polymer 229F, 231F encase the polymer and flat wire elongate members 207F, 207G. The polymer layers 229F, 231F are preferably softer than the polymer material of the elongate member 207F. The polymer layers 229F, 231F are preferably 80A polyurethane, however, any polymer may be used. The polymer layers 229F, 231F may be applied in any manner described above. The polymer layers 229F, 231F preferably have a thickness between 0.002 and 0.010 inch and more preferably between 0.004 and 0.008 inch. The polymer layers 229F, 231F are heated to bond to the polymer elongate member 207. Fig. 13 depicts the reinforced section 205 before heating, however, after heating the layers 229F, 231F and elongate member 207F fuse together to form an integrated structure.

Referring to Fig. 15, an eighth preferred construction for the reinforced section 205 is shown. A first elongate member 207H is preferably the same as the elongate member 207A described above in connection with Fig. 10. A second elongate member 207J is made of a polymer and has a thickness between 0.003 and 0.008 inch and more preferably 0.005 inch. Two polymer layers 229H, 231H encase the elongate members. The layers 229H, 231H are preferably 80A polyurethane having a thickness between 0.002 and 0.010 inch and more preferably between 0.004 and 0.008 inch. The polymer layers 229H, 231H may be applied in any manner described above. The polymer layers 229H, 231H are heated to bond to the second elongate member 207J.

Referring to Fig. 16, a ninth preferred construction for the reinforced section 205 is shown. A first elongate member 207L is wound around a mandrel 213 (not shown). The first elongate member 207L is preferably made of polymer, preferably 80A polyurethane, and has a T-shaped cross-sectional shape. The T-shaped cross-sectional shape has a width of 0.028 inch and a height of 0.008 inch. The first elongate member 207L has a radial extension 233 having a width of 0.008 inch. A second elongate member 207M, which is

preferably the same as the elongate member 207A described above in connection with Figs. 70, is wound over the first elongate member 207L. A polymer layer 229L is then positioned over the first and second elongate members 207L, 207M and is 5 preferably 80A polyurethane having a thickness of 0.008 inch. The polymer layer 229L may be applied in any manner described above. The polymer layer 229L is then heated so that the polymer layer 229L and the radial extension 233 bond to one another to form an integrated structure.

10 Referring to Fig. 17, another preferred cannula 301 is shown. The cannula 301 is preferably used as the arterial return cannula for the CPB system described above. The cannula 301 includes the reinforced section 205 as described above. A tube 303 connects the reinforced section 205 to a Y-
15 connector 305 which has first, second and third connections 307, 309, 311. The tube 303 is preferably a flexible tube made of estane 58810 42D polyether polyurethane. When using the cannula 301 for the CPB system described above, the first connection 307 is coupled to a source of oxygenated blood (not shown) while the second connection 309 receives an aortic occlusion catheter (not shown). The aortic occlusion catheter is used to occlude the ascending aorta and deliver cardioplegic fluid for arresting the patient's heart. The second connection 309 preferably receives the extension tube 20 62 and hemostasis valve 876 for receiving the aortic occlusion catheter in the manner described above in connection with 25 Figs. 1-4.

30 A dilator 313 is used to facilitate introduction of the cannula 301 into the patient's artery. A dilator seal 315 seals the space between the cannula 301 and dilator 313. The dilator seal 315 and dilator 313 are removed after the cannula 301 has been introduced into the patient. Referring to Fig. 20, the end of the dilator 313 has an enlarged end 319 which engages an interior wall of the reinforced section 205 when 35 passing through the cannula 301. The enlarged end 319 is preferred so that the dilator 313 does not contact the cannula 301 throughout the length of the dilator 313 thereby reducing

the resistance to moving the dilator 313 through the cannula 301.

Referring to Fig. 18, the method of forming the reinforced section 205 is shown. The reinforced section 205 has an elongate member 207N coated with a coating 209N with the elongate member 207N and coating 209N being any of the members 207A-M and coatings 209A-M described above in connection with Figs. 6-16. A preferred elongate member 207N is a 0.008 inch stainless steel wire which is coated with 80A durometer polyurethane to a 0.014 x 0.014 inch cross-section. The elongate member 207N is wrapped around a mandrel (not shown), as described above in connection with Figs. 6-16, and a soft tip 221N is butted against the elongate member 207N. The soft tip 221N preferably has the same thickness as the 15 coated elongate member 207N with a preferred material being 90A polyurethane.

A layer 225N, which may be the layer 225 described above, is positioned over the coated elongate member 207N and the soft tip 221N. The layer 225N is preferably a tube having a thickness of 0.001-0.005 inch, more preferably about 0.003 inch, and is preferably made of the same material as the soft tip 221N. Although it is preferred to provide the layer 225N over the coated elongate member 207N it is understood that the layer 225N may also be positioned on the radially inner 20 surface of the coated elongate member 207N (or not used at all). When the layer 225N is a tube, the tube has an inner diameter which is slightly smaller than the smallest outer diameter of the reinforced section 205. The tube is positioned over the reinforced section by inflating the tube, 25 inserting the coated elongate member 207N into the tube, and deflating the tube so that the tube contracts around the helically wound coated elongated member 207N. By sizing the layer 225N somewhat smaller than the helically wound elongate member 207N, close contact between the layer 225N and elongate member 207N is ensured.

A heat shrink tube (not shown) is then positioned over the layer 225N, coated elongate member 207N, and soft tip 221N. The layer 225N, coated elongate member 207N and soft

tip 221N are then heated to fuse the material together to form an integral structure as shown in Fig. 19. The tip of the reinforced member 205 is then trimmed and a tapered mandrel is inserted into coated elongate member and a heat shrink tube is recovered over the tip to form a bevel 317 at an end 319 of the soft tip 221N which facilitates atraumatic insertion of the cannula 301. The end 319 is curved inward slightly to form a seal with the dilator 313.

The resulting reinforced section 205 preferably has an internal diameter of at least 0.180 inch, more preferably at least 0.200 inch, more preferably at least 0.236 and most preferably at least 0.242 but no more than 0.375 inch. The reinforced section 205 also preferably has a thickness of no more than 0.0020 inches, more preferably no more than 0.018 inches, and most preferably no more than 0.016 inch. When the coated elongate member 207N has a 0.014 x 0.014 inch exterior surface and the layer 225N has a 0.003 inch thickness the resulting thickness is about 0.0016 inch since about 0.001 inch is lost when the coated elongate member 207N and layer 225N are compressed with the shrink tube during heating. The unique combination of inner diameter and wall thickness provides an excellent cannula.

The methods and devices disclosed herein have been described in conjunction with cannulas, however, it is understood that the methods and apparatus may also be used for constructing any other hollow tubes including catheters and the like. While the above is a preferred description of the invention, various alternatives, modifications and equivalents may be used without departing from the scope of the invention. For example, the opposing sides of the coated elongate member 207 may have an S-shape, and the reinforced section 205 may have a varying wall thickness. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the claims.

WHAT IS CLAIMED IS:

- 1 1. A method of manufacturing a hollow tube,
2 comprising the steps of:
 - 3 coating an elongate member with a material thereby
4 forming a coated elongate member;
 - 5 winding the coated elongate member around a mandrel;
 - 6 heating the coated elongate member after the winding
7 step;
 - 8 removing the coated elongate member from the
1 mandrel.
- 1 2. The method of claim 1, further comprising the
2 step of:
 - 3 compressing the coated elongate member after the
4 winding step and before the removing step.
- 5 3. The method of claim 1, wherein:
6 the coating step is carried out by coextruding the
7 material over the elongate member.
- 1 4. The method of claim 1, wherein:
2 the coating step is carried out with the material
3 being a substance selected from the group consisting of
4 thermoplastics.
- 1 5. The method of claim 1, wherein:
2 the coating step is carried out with the material
3 being a material selected from the group consisting of
4 polyurethane, polyether block amide and PVC.
- 1 6. The method of claim 1, further comprising the
2 step of:
 - 3 dipping the mandrel in a solution after the winding
4 step.

5 7. The method of claim 1, wherein:
6 the coating step is carried out so that the coated
7 elongate member has a polygonal-shaped cross-section.

8 8. The method of claim 7, wherein:
9 the coextruding step is carried out so that the
10 polygonal-shaped cross-section is a quadrangle

11 9. The method of claim 1, wherein:
12 the wrapping step is carried out with the mandrel
13 having a circular cross-sectional shape.

1 10. The method of claim 9, wherein:
2 the wrapping step is carried out with the circular
3 cross-sectional shape of the mandrel having a radius which
4 varies along the longitudinal axis.

1 11. The method of claim 1, wherein:
2 the coating step is carried out with the elongate
3 member being a metal wire.

1 12. The method of claim 1, wherein:
2 the heating step is carried out by heating the
3 mandrel.

1 13. The method of claim 1, further comprising the
2 step of:
3 positioning a layer on at least one of a radially
4 inner and a radially outer side of the coated elongate member.

1 14. The method of claim 13, wherein:
2 the positioning step is carried out with the layer
3 being a tube of material.

4 15. A cannula comprising:
5 a body having a first lumen; and
6 a reinforced section coupled to the body, the
7 reinforced section having a second lumen fluidly coupled to

8 the first lumen thereby providing a fluid flow path, the
9 reinforced section having a longitudinal length of at least 1
10 inch and a wall thickness of no more than 0.020 inch, the
11 reinforced section having an elongate reinforcing member
12 configured in a helical pattern and encased in a material, the
13 second lumen having a diameter of at least 0.180 inch.

1 16. The cannula of claim 15, wherein:
2 the material encasing the elongate reinforcing
3 member is a polymer.

1 17. The cannula of claim 15, wherein:
2 the reinforced section has a thickness of no more
3 than 0.018 inch.

1 18. The cannula of claim 15, wherein:
2 the reinforced section has a thickness of no more
3 than 0.008 inch.

1 19. The cannula of claim 15, wherein:
2 the second lumen has an inner diameter of at least
3 0.200 inch.

4 20. The cannula of claim 15, wherein:
5 the second lumen has an inner diameter of at least
6 0.236 inch.

7 21. The cannula of claim 15, wherein:
8 the body includes a third lumen fluidly coupled to
9 the second lumen.

10 22. A cannula for delivering and/or withdrawing
11 fluids from a patient, comprising:
12 a reinforced section having a first elongate member
13 and a second elongate member, the first and second elongate
14 members having helical shapes, the first and second elongate
15 members being positioned side by side, the first and second

16 elongate members being encased in a material, the reinforced
17 section having a first lumen; and
18 a body coupled to the reinforced section, the body
19 having a second lumen fluidly coupled to the first lumen.

1 23. The cannula of claim 22, wherein:
2 the first elongate member is made of a polymer and
3 the second elongate member is made of metal.

1 24. The cannula of claim 22, wherein:
2 the reinforcing section includes a third elongate
3 member, the third elongate member also being positioned side
4 by side with the first and second elongate members.

1 25. The cannula of claim 22, wherein:
2 the first elongate member has a quadrangle cross-
3 sectional shape.

1 26. The cannula of claim 22, wherein:
2 the second elongate member is made of a first
3 polymer; and
4 the material encasing the first and second elongate
5 members is a second polymer, the second polymer being softer
6 than the first polymer.

1 27. A cannula for delivering and withdrawing fluids
2 from a patient, comprising:
3 a reinforced section having an elongate member
4 encased in a first polymer material, the elongate member
5 having a helical shape and being made of a second polymer
6 material, the reinforced section having a first lumen; and
7 a body having a second lumen fluidly coupled to the
8 first lumen, the body being coupled to the reinforced section.

9 28. The cannula of claim 27, wherein:
10 the second polymer material is harder than the first
11 polymer material.

12 29. The cannula of claim 27, wherein:
13 the elongate member has a circular cross-sectional
14 shape and a diameter of between 0.008 and 0.012 inches, the
15 first polymer material having a thickness of between 0.005 and
16 0.010 inches.

1 / 11

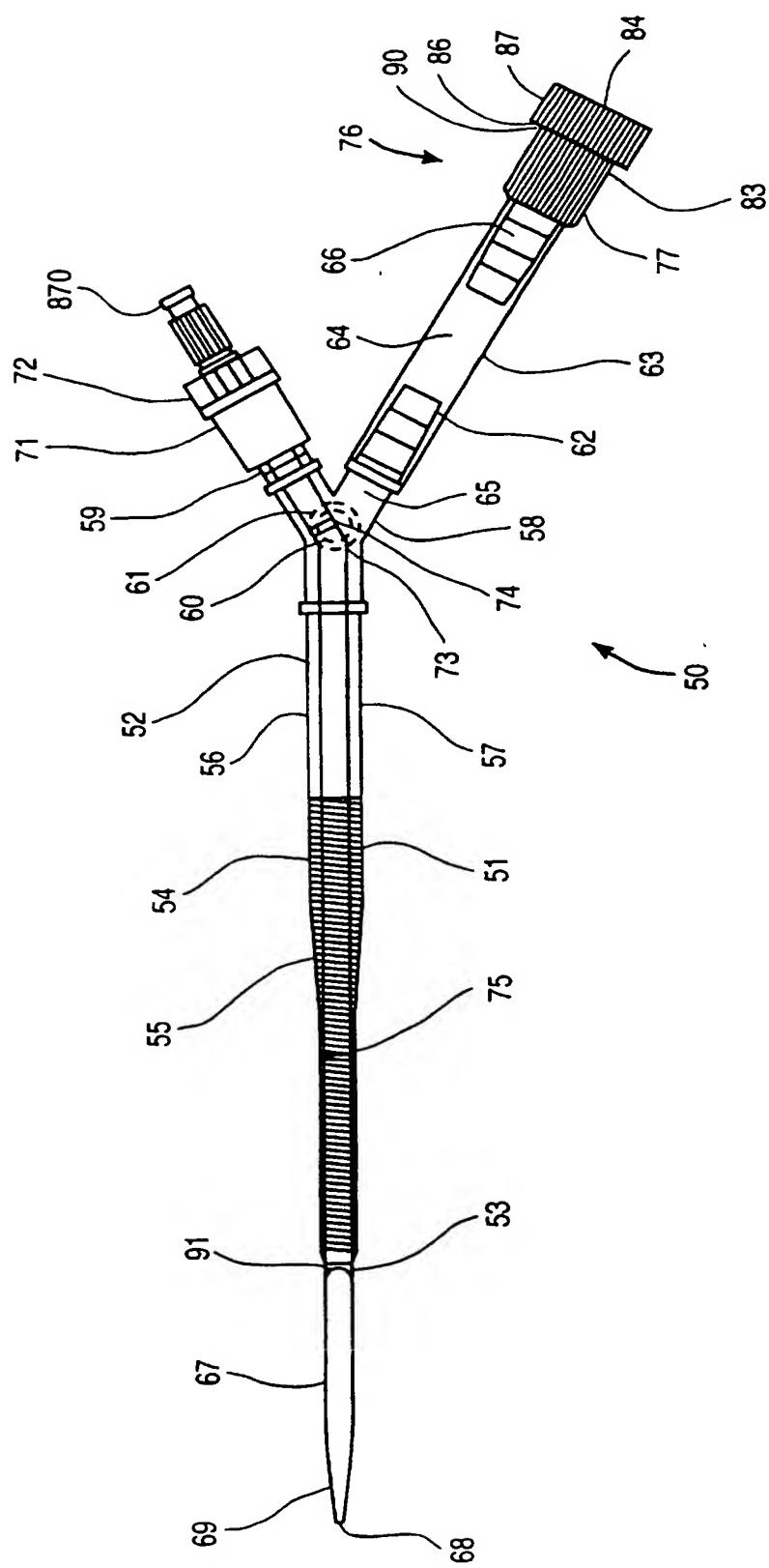


FIG. 1

SUBSTITUTE SHEET (RULE 26)

2 / 11

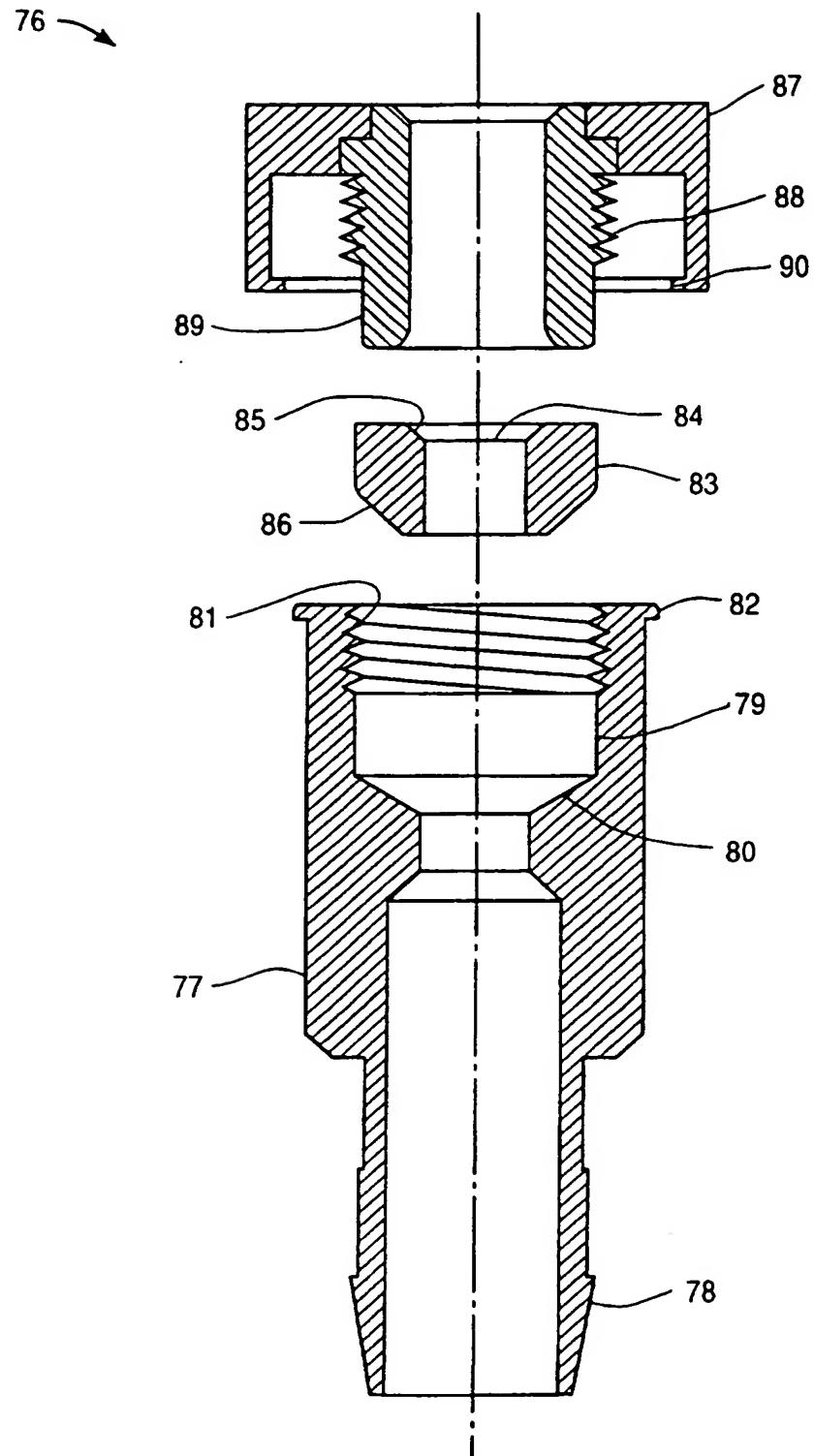


FIG. 2

SUBSTITUTE SHEET (RULE 26)

3 / 11

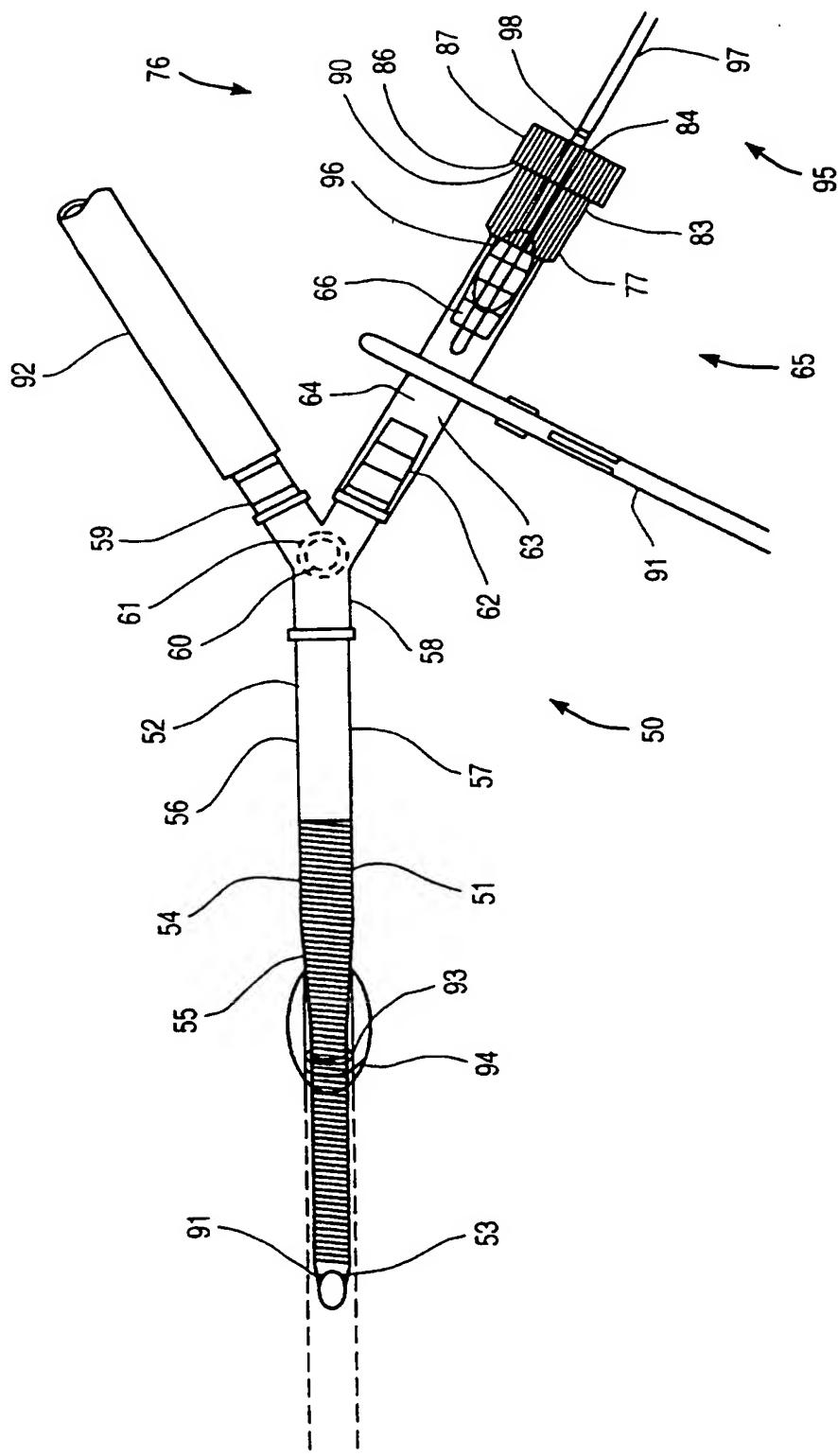


FIG. 3

SUBSTITUTE SHEET (RULE 26)

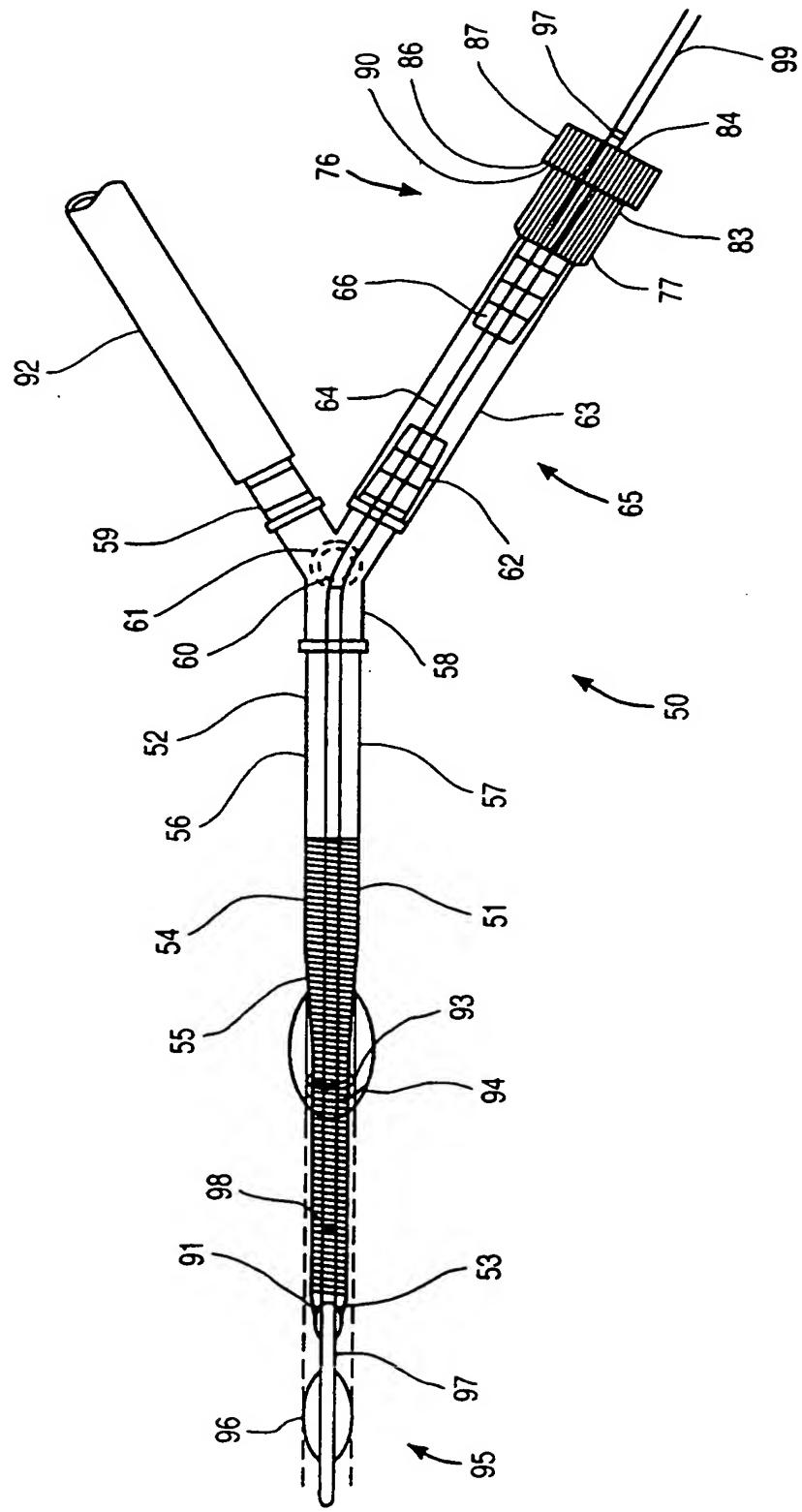


FIG. 4

SUBSTITUTE SHEET (RULE 26)

5 / 11

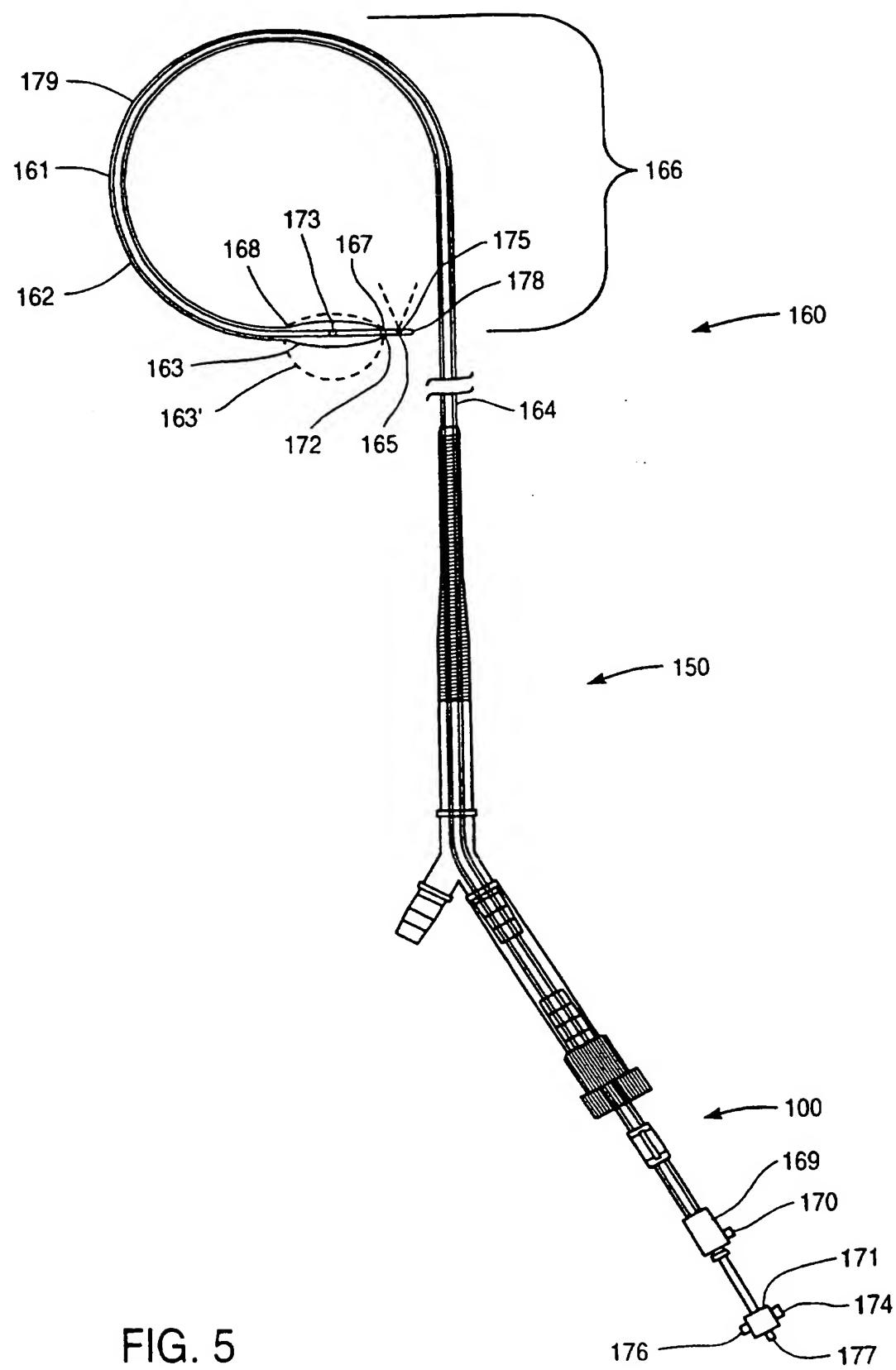


FIG. 5

SUBSTITUTE SHEET (RULE 26)

6 / 11

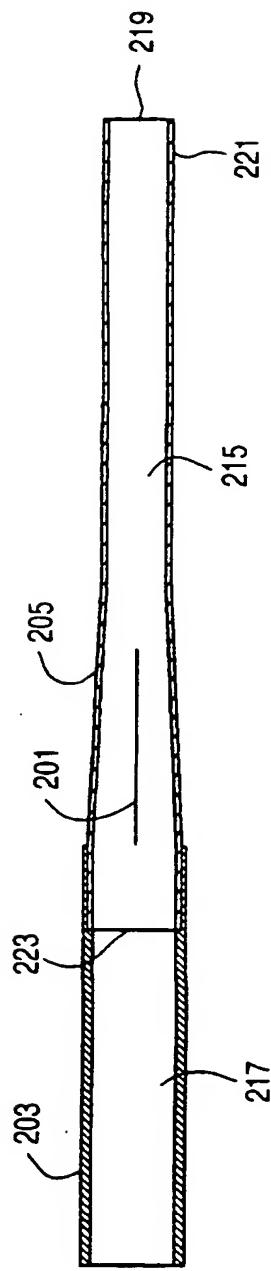


FIG. 6

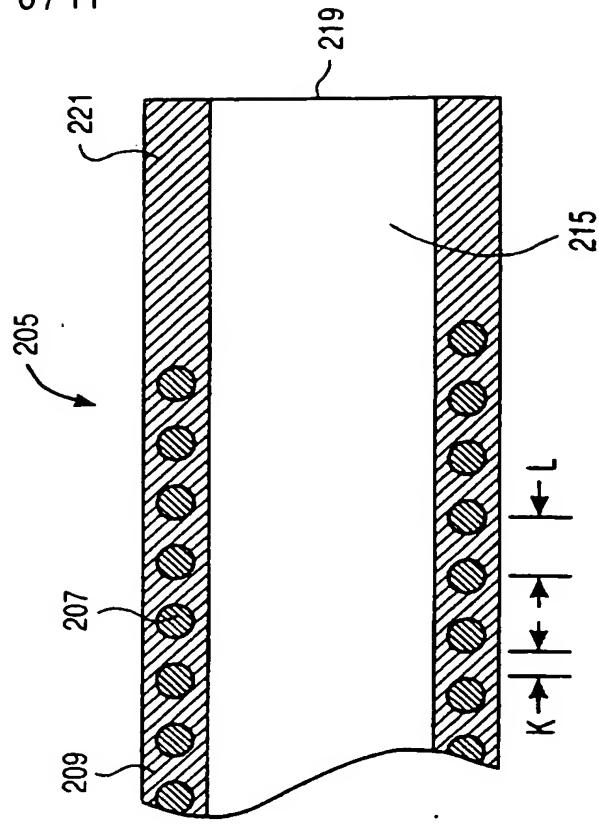


FIG. 8

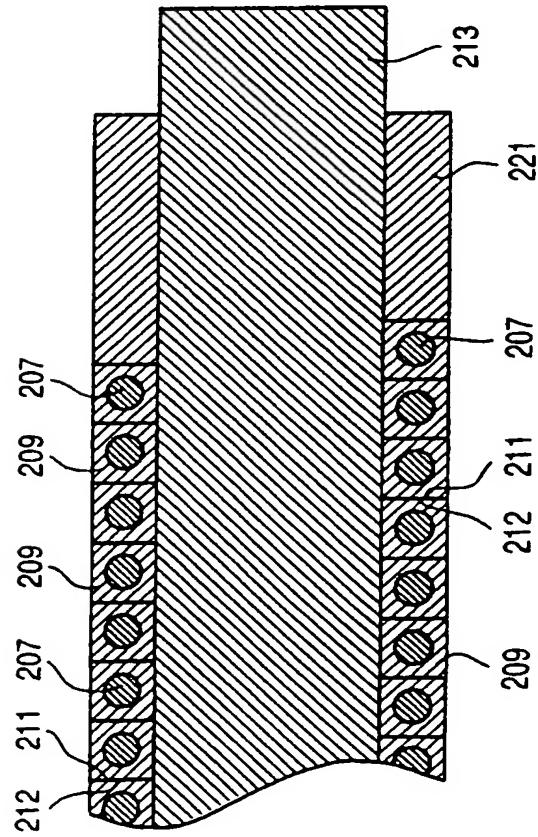
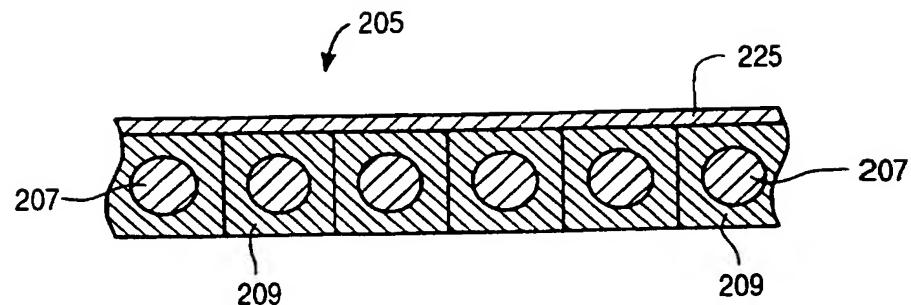
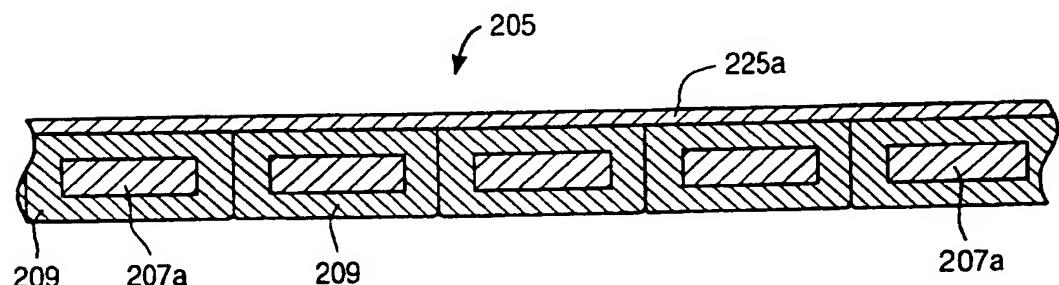
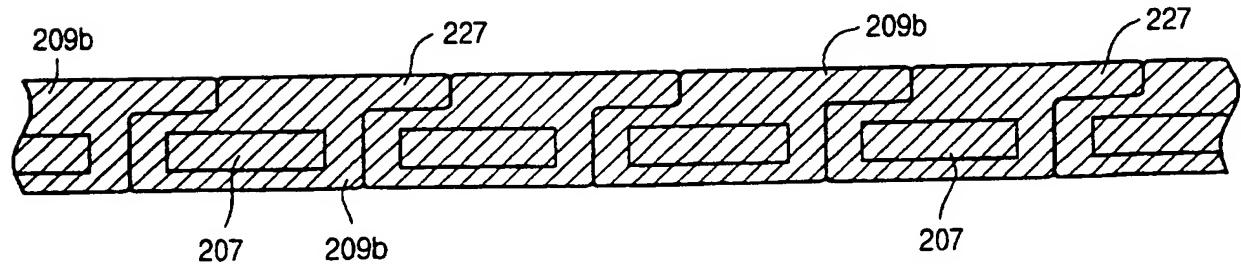


FIG. 7

SUBSTITUTE SHEET (RULE 26)

7 / 11

**FIG. 9****FIG. 10****FIG. 11****SUBSTITUTE SHEET (RULE 26)**

8 / 11

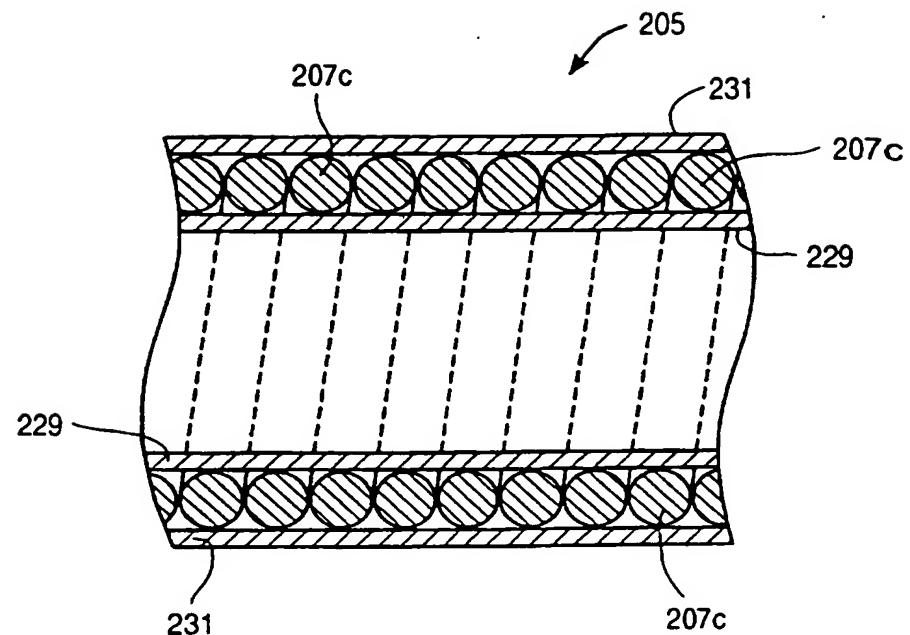


FIG. 12

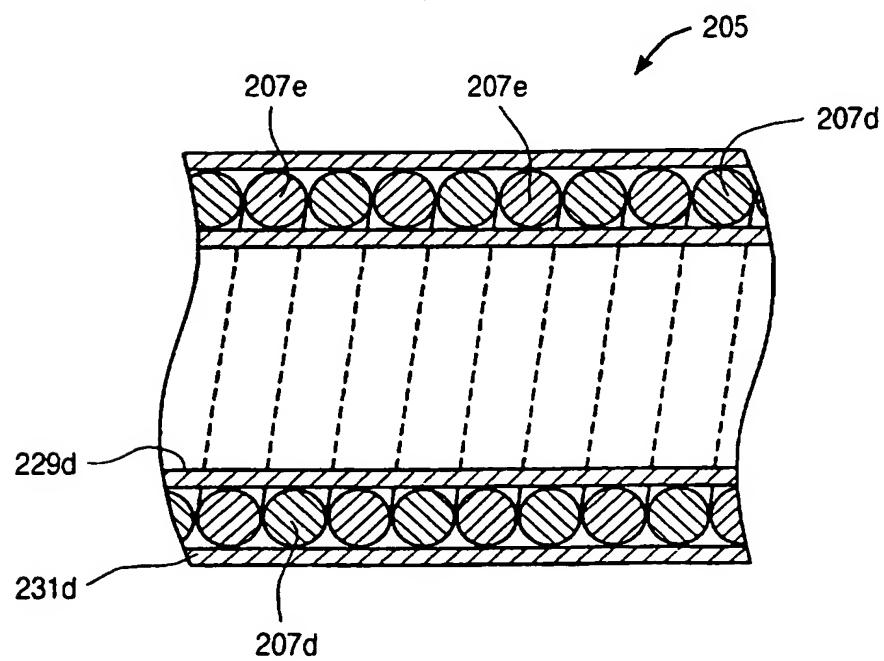
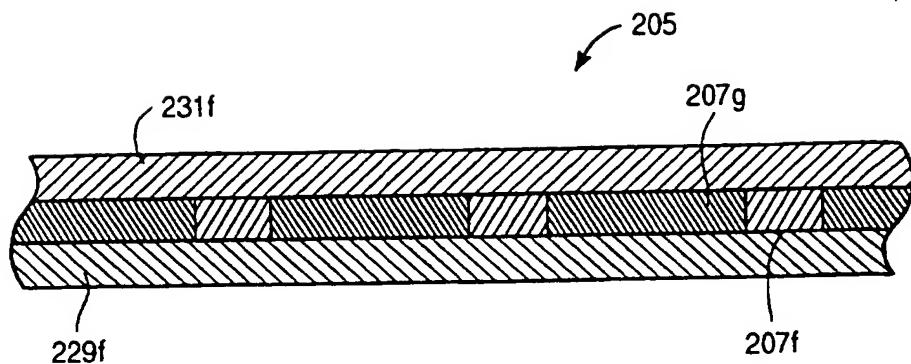
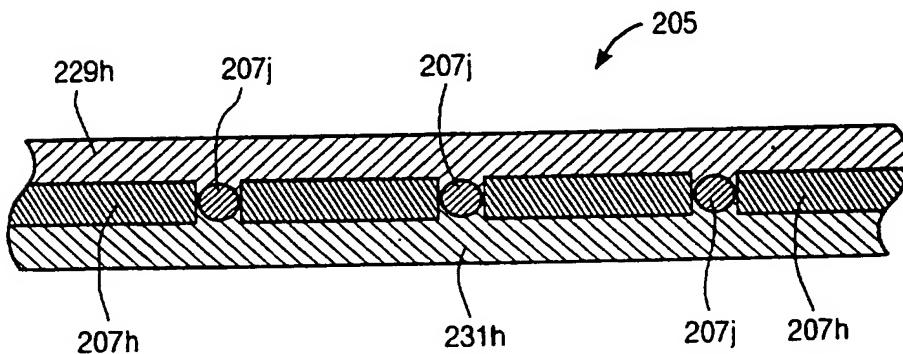
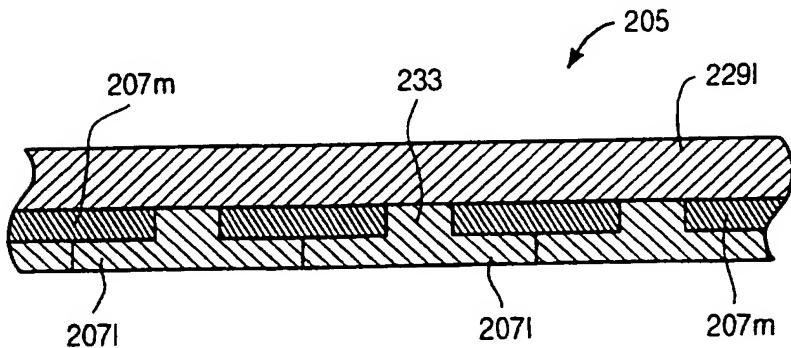


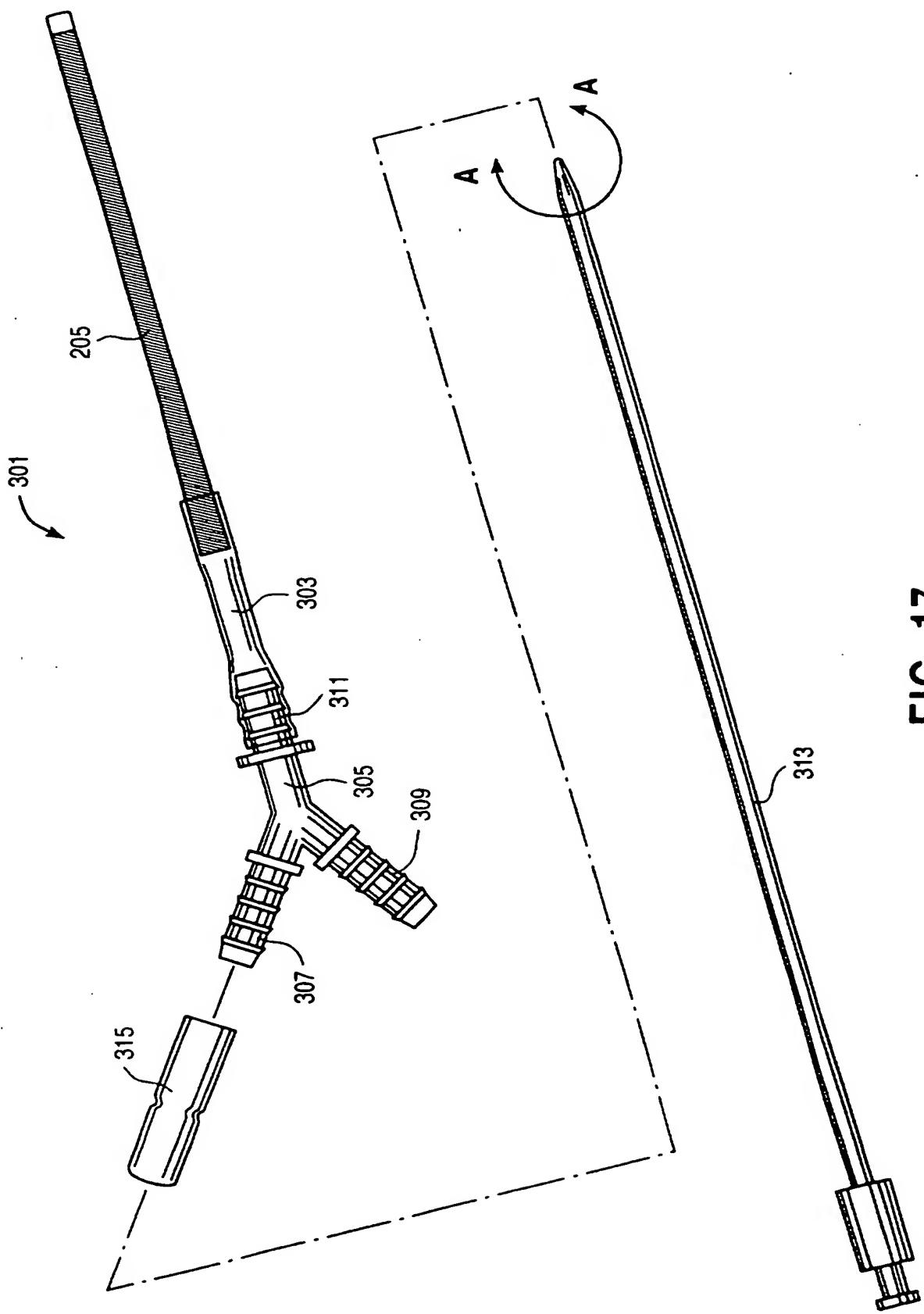
FIG. 13

SUBSTITUTE SHEET (RULE 26)

9 / 11

**FIG. 14****FIG. 15****FIG. 16****SUBSTITUTE SHEET (RULE 26)**

10 / 11



SUBSTITUTE SHEET (RULE 26)

11 / 11

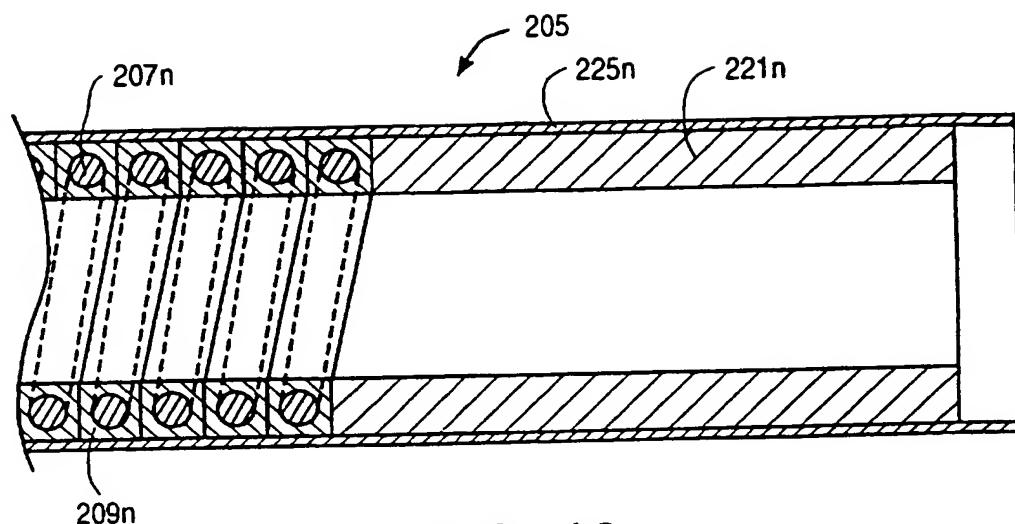


FIG. 18

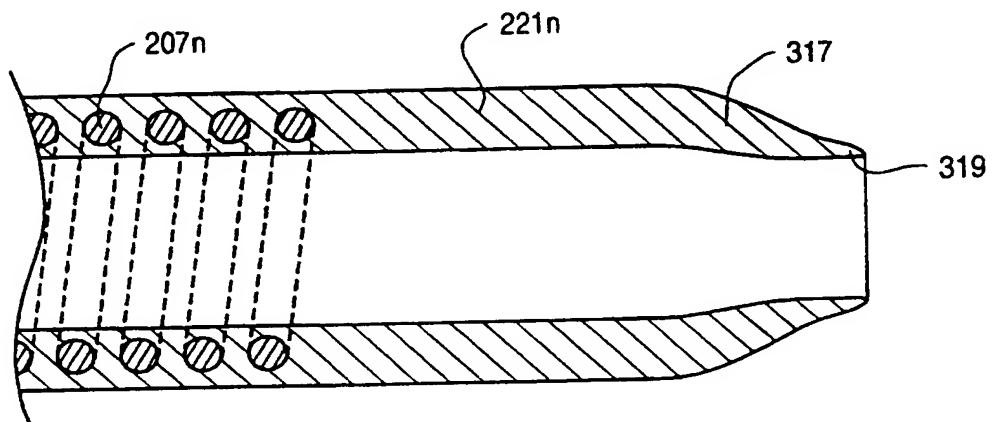


FIG. 19

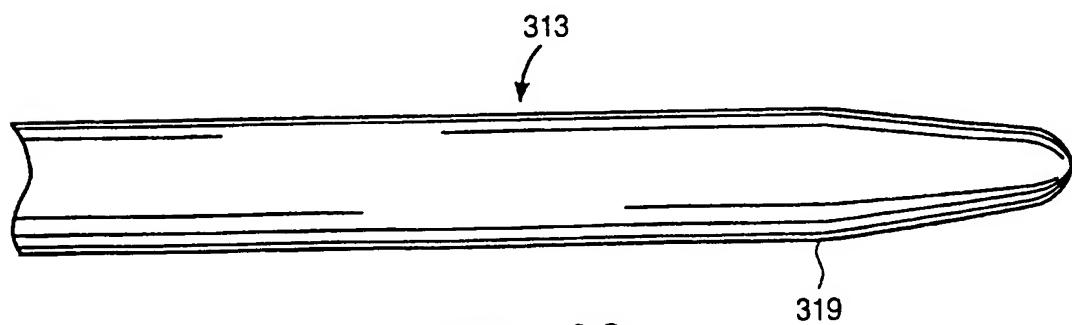


FIG. 20

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/03543

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00

US CL :604/282

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 87/8.9; 138/118, 123, 129, 132, 172; 604/264, 280, 282

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

Search Terms: tube, heat, mandrel, manufacture, braid, wind, reinforce

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, 4,842,590 A (TANABE et al) 27 June 1989, col. 4, lines 42-52; and Fig. 6.	15-17, 21, 22, 24
---		-----
Y	US 5,176,660 A (TRUCKAI) 05 January 1993, col. 4, lines 1-4.	23, 25-29
Y	US 5,176,660 A (TRUCKAI) 05 January 1993, col. 4, lines 1-4.	23, 25-29
A	US 4,899,787 A (OUCHI et al.) 13 February 1990, Abstract.	1-29
A,P	US 5,538,513 A (OKAJIMA et al) 23 July 1996, Abstract.	1-29
A,P	US 5,591,142 A (VAN ERP) 07 January 1997, Abstract.	1-29

Further documents are listed in the continuation of Box C.

See patent family annex.

• Special categories of cited documents:	
• A* document defining the general state of the art which is not considered to be of particular relevance	• T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
• E* earlier document published on or after the international filing date	• X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
• L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	• Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
• O* document referring to an oral disclosure, use, exhibition or other means	• Z* document member of the same patent family
• P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

25 APRIL 1997

Date of mailing of the international search report

12 MAY 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer
CORRINE M. MCDERMOTT

Telephone No. (703) 308-2111

Form PCT/ISA/210 (second sheet)(July 1992)*

THIS PAGE BLANK (USPTO)